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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/015,078	01/29/98	SUERBAUM	S 2356-0073-01

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WASHINGTON DC 20005-3315

EXAMINER

TURNER, S

ART UNIT	PAPER NUMBER
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1644

DATE MAILED: 05/10/00

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.
09/015,078

Applicant(s)

Suerbaum

Examiner

Sharon L. Turner, Ph.D.

Group Art Unit
1644



☒ Responsive to communication(s) filed on 2-25-00

☐ This action is **FINAL**.

☐ Since this application is in condition for allowance except for formal matters, **prosecution as to the merits is closed** in accordance with the practice under *Ex parte Quayle*, 35 C.D. 11; 453 O.G. 213.

A shortened statutory period for response to this action is set to expire 3 month(s), or thirty days, whichever is longer, from the mailing date of this communication. Failure to respond within the period for response will cause the application to become abandoned. (35 U.S.C. § 133). Extensions of time may be obtained under the provisions of 37 CFR 1.136(a).

Disposition of Claim

☒ Claim(s) 31-42 is/are pending in the application.
Of the above, claim(s) 31-36 is/are withdrawn from consideration

☐ Claim(s) _____ is/are allowed.

☒ Claim(s) 37-42 is/are rejected.

☐ Claim(s) _____ is/are objected to.

☐ Claims _____ are subject to restriction or election requirement.

Application Papers

☐ See the attached Notice of Draftsperson's Patent Drawing Review, PTO-948.

☐ The drawing(s) filed on _____ is/are objected to by the Examiner.

☐ The proposed drawing correction, filed on _____ is ☐ approved ☐ disapproved.

☐ The specification is objected to by the Examiner.

☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).

☐ All ☐ Some* ☒ None of the CERTIFIED copies of the priority documents have been
☐ received.

☐ received in Application No. (Series Code/Serial Number) _____

☐ received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

*Certified copies not received: _____

☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

☒ Notice of References Cited, PTO-892

☒ Information Disclosure Statement(s), PTO-1449, Paper No(s). 4

☐ Interview Summary, PTO-413

☐ Notice of Draftsperson's Patent Drawing Review, PTO-948

☐ Notice of Informal Patent Application, PTO-152

--- SEE OFFICE ACTION ON THE FOLLOWING PAGES ---

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Response to Amendment

1. The Examiner of U.S. Patent application SN 09/015,078 has changed. In order to expedite the correlation of papers with the application please direct all future correspondence to Examiner Turner, Technology Center 1600, Art Unit 1644.
2. The amendment filed 2-25-00 has been entered into the record and has been fully considered. Figures 1-13 have been entered. The missing references and relevancy statements have been supplied and have been considered as indicated on the PTO-1449.
3. Claims 31-42 are pending. Claims 31-36 are withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to nonelected inventions, there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in Paper No. 7.
4. As a result of applicants amendment, all rejections not reiterated herein have been withdrawn by the examiner.

Rejections Maintained

Priority

5. Acknowledgment is made of applicant's claim for foreign priority based on an application filed in France on April 7, 1995. It is noted, however, that applicant has not filed a certified translated copy of the 95 08068 application as required by 35 U.S.C. 119(b).
6. The examiner notes that the specification has been amended as requested inserting reference to the above application, however the reference refers to the application as being filed

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on July 4, 1995 which is believed to be the incorrect date of filing due to conflict with that which is in the oath as April 7, 1995. Correction is required.

Claim Rejections - 35 USC § 112

7. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

8. Claim 37-38 stand rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Applicants argue that one of ordinary skill in the art would readily understand that the nucleotide sequence hybridizes with a probe and additionally that the probe has been amplified using two oligonucleotide sequences and that thus the claim particularly points out and distinctly claims the invention.

Applicant's arguments filed 2-25-00 have been fully considered but they are not persuasive. The claim remains indefinite in the following regards. In part a), the statement "or of a nucleotide sequence of a flbA gene..." may refer to what the sample is brought into contact with or alternatively to a particular deletion. The statement "which has been amplified using two..." may refer either to a nucleotide sequence of a flbA gene or to the nucleotide probe which corresponds to a fragment of *H. pylori*. The statement "or able to hybridize, under conditions of high stringency, with these nucleotides" may refer to the nucleotides of the flbA gene, the

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nucleotides which hybridize to the flbA gene, the probe, or the nucleotides of SEQ ID NO:1. The examiner has interpreted part b) of the claims as detecting an immunological reaction between the bacterial strain or the bacterial extract wherein the immunological reaction is detected by antibodies and the antibodies are present in the sample. The claim remains indefinite because the multiple uses of "or", "which" and reference to multiple nucleotide sequences as "these nucleotides". Such ambiguous limitations lack sufficient antecedent basis to clearly delineate the claimed elements or steps of the recited method. Applicants are advised that terminology such as "said" may aid in reference to particular elements to provide proper antecedent basis. Applicant is also advised that a list of alternatives may be used as in a Markusch but should be linked by "and" instead of "or". The method should clearly delineate the steps involved in the method and the limitations of the various reagents.

Claim Rejections - 35 USC § 102

9. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless --

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

10. Claims 37-39 and dependent claims 40-42 stand rejected under 35 U.S.C. 102(b) as being by anticipated by Haas et al., Mol. Microbiol., 1993, 8(4):753-60.

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Applicants argue that Haas' general method of generating defined mutants in *H. pylori* does not constitute a method of detecting an infection in a sample from a patient and that in particular Haas et al does not teach a method for the *in vitro* detection of an infection due to *H. pylori* in a sample of biological fluid from a patient comprising a) bringing the sample into contact with a bacterial strain ... and b) detecting an immunological reaction between the bacterial strain and antibodies which are directed against *H. pylori* and which are present in the sample, as recited in the claims.

Applicant's arguments filed 2-25-00 have been fully considered but they are not persuasive. Contrary to applicants assertion Haas does teach a method for the *in vitro* detection of an infection due to *H. pylori* in a sample of biological fluid from a patient comprising a) bringing the sample into contact with a bacterial strain ... and b) detecting an immunological reaction between the bacterial strain and antibodies which are directed against *H. pylori* and which are present in the sample, as recited in the claims. In particular, the patient is a rabbit. The patients antisera constitutes biological fluid. The antisera (sample) is brought into contact with a bacterial strain or extract of a bacterial strain which is aflagellate (69A-derived flaA mutants P4 and P5). The bacterial strains and extract in contact with the rabbit biological sample is expressly depicted in Figure 4 which show the detection of an immunological reaction between the bacterial strain and antibodies directed against *H. pylori*., and the antibodies are present in the biological (sera) sample. Thus, the reference teachings anticipate the claimed invention.

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New Rejections

11. Claim 42 is rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

Claim 42 recites the limitation "the nucleotide sequence" in reference to claim 37 or 38. There is multiplicative antecedent basis for this limitation in the claims. Thus, the claims are confusing and indefinite because there is no direction as to which sequence in claims 37 and 38 are further limited to SEQ ID NO:6, i.e., the probe, the gene or the primers.

12. Claims 37-39 are rejected under 35 U.S.C. 102(b) as being anticipated by O'Toole et al., , Mol. Microbiol., 1994, 14(4):691-703.

O'Toole teaches a method for the *in vitro* detection of an infection due to *H. pylori* in a sample of biological fluid from a patient comprising a) bringing the sample into contact with a bacterial strain or a bacterial extract from said bacterial strain wherein the strain is aflagellate and lacks the flagellar hook protein ... and b) detecting an immunological reaction between the bacterial strain and antibodies which are directed against *H. pylori* and which are present in the sample, as recited in the claims. The biological sample is rabbit antisera and the bacterial strain or extract is from *H. pylori* flgE mutants which are aflagellate and lack the hook protein, see in particular Figures 2, 6 and 8 for immunological detection via antibodies contained in the serum sample and bacterial extracts. Thus, the reference teachings anticipate the claimed invention.

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13. Claims 40-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over either Haas et al., Mol. Microbiol., 1993, 8(4):753-60 or O'Toole et al, Mol. Microbiol., 1994, 14(4):691-703 as applied to claims 37-39 above, and further in view of Lelwala-Guruge et al., Scan. J. of Infect. Dis., 1992, 24(4):457-65.

Haas et al and O'Toole et al are set forth above.

Neither Haas or O'Toole teach bacterial extract obtained after extracting with n-octyl glucoside, PBS or glycine as claimed in claims 40-41.

Lelwala-Guruge teach extraction of *H. pylori* proteins with acidic glycine buffer, N-octyl-glucoside, lithium chloride and distilled water and by sonication, see in particular abstract, for preparation of antigens for immunological detection via an ELISA. Thus, it would have been prima facie obvious to one of skill in the art at the time the invention was made that one could incorporate the method of Lelwala-Guruge et al for extraction of *H. pylori* proteins using acidic glycine buffer, N-octyl-glucoside, lithium chloride and distilled water and by sonication to prepare the aflagellate strains of claims 37-38 for immunological detection. One of skill in the art would have been motivated to do and expected success as taught by Lelwala-Guruge et al because the extraction procedure provides for high sensitivity, and specificity in immunoblotting *H. pylori* antigens. Thus, the combined reference teachings render the claimed invention obvious.

Status of Claims

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14. No claims are allowed.

Conclusion

15. Any inquiry of a general nature or relating to the status of this general application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Papers relating to this application may be submitted to Technology Center 1600, Group 1640 by facsimile transmission. The faxing of such papers must conform with the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). Should applicant wish to FAX a response, the current FAX number for Group 1600 is (703) 308-4242.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Sharon L. Turner, Ph.D. whose telephone number is (703) 308-0056. The examiner can normally be reached on Monday-Friday from 8:00 AM to 4:30 PM. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christina Chan can be reached at (703) 308-3973.

Sharon L. Turner, Ph.D.
May 7, 2000

Patricia A. Duffy
PATRICIA A. DUFFY
PRIMARY EXAMINER